



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/825,522

04/15/2004

Gary K. Michelson

101.0069-02000

8146

22882 7590 09/01/2009
MARTIN & FERRARO, LLP
1557 LAKE O'PINES STREET, NE
HARTVILLE, OH 44632

EXAMINER

WILLSE, DAVID H

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,522	Applicant(s) MICHELSON, GARY K.	
	Examiner David H. Willse	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-5-09</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3738

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The newly claimed range with the lower limit “one-half the length of the implant” (e.g., amended claim 1, lines 14-15) is not supported in the original disclosure (MPEP § 2163.05, section III). Attention is directed, for example, to Figures 5 and 7 and original claim 86 of grandparent application serial no. 09/566,272.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Brosnahan, US 5,645,598, and Michelson, US 5,593,409, and further in view of Brantigan, US 4,834,757, or Brantigan, US 5,192,327. Brosnahan discloses providing a first

Art Unit: 3738

implant (Figure 14) in the form of a threaded partial cylinder having opposite arcuate portions **44** and **46** adapted for placement toward and at least in part within adjacent vertebral bodies (column 2, lines 35-40; column 5, lines 2-6; Figure 1; etc.), providing a second implant **10** or **10A** or **10B**, forming first and second partially overlapping cylindrical holes across the disc space (column 5, lines 46-49 and 55-58), and threading the implants into the holes so as to be nested closely (column 5, line 47; column 2, lines 29-31; column 4, lines 44-46; etc.).

The embodiment of Figures 10-13 includes a hollow interior **40** filled with porous material **42** (column 5, lines 31-45), but Brosnahan lacks openings in the side walls. However, openings throughout cylindrical and partial cylindrical surfaces were quite common in the art, as seen, for example, from Michelson '409, the ancestor application of which is referenced by Brosnahan at column 1, lines 37. Although Brosnahan discusses disadvantages of bone grafting (column 1, line 44 et seq.), such a practice is nonetheless widely used, and as seen from both Brosnahan and Michelson '409 (at column 10, lines 8-12 and 35-39, for example), *artificial* materials may alternatively be used. Therefore, the Brosnahan first and second implants being perforated and hollowed in a manner illustrated in the drawings of Michelson '409 would have been an obvious variant in order to enhance fusion throughout the occupied disc space and in order to increase implant stability (Michelson '409: column 4, lines 33-35). Likewise, although Michelson '409 lists various disadvantages of screw threads, such are nevertheless very common, and as seen from the "nested" embodiment of Brosnahan, which is similar to the upper embodiment depicted in Figure 43 of Michelson '409, some of these disadvantages are overcome, and threaded implants do not require impacting with a mallet (Michelson '409: column 10, line 57-60). Thus threaded versions of the Michelson '409 implants **900a** and **900b**

Art Unit: 3738

would have been obvious (even if such is an obvious step backward relative to the Michelson '409 disclosure taken alone).

Regarding the newly added limitation pertaining to a medial side opening "having a dimension greater than one-half the length of the implant" (e.g., instant claim 1, lines 14-15), superior-inferior and medial-lateral through openings of such a relative length were well known in the art at the time of the present invention, as seen from the drawings of Brantigan '757 or Brantigan '327. To incorporate one or more of such openings into Brosnahan and Michelson '409 would have been obvious in order to facilitate bone growth "all around and through the implant plug into the bone of the vertebrae" (Brantigan '757: column 3, lines 54-63; column 3, lines 33-36; column 6, lines 62-65; column 7, lines 20-23; etc.) and/or in order to provide "ample spaces to allow ingrowth of blood capillaries and packing of bone graft" (Brantigan '327: abstract, lines 15-17; column 2, lines 52-55; column 4, lines 54-56; column 7, lines 21-23; etc.), with further motivation having been provided by both Brosnahan (e.g., figures and abstract) and Michelson '409 (column 10, lines 12-16; column 13, lines 9-13; column 14, lines 27-28) similarly teaching elongated slots for such purposes.

Regarding claim 1 and others, the aforementioned "nested" embodiment being installed such that the mid-longitudinal axes converge to one another would have been immediately obvious, if not inherent, from Figure 2 of Brosnahan in order to better conform the trailing ends of the implants to the outer contour of the vertebrae. Regarding claim 3 and others, tapping prior to insertion of the implants would have been obvious to the ordinary practitioner in order to facilitate or ease the action of the screwdriver (Brosnahan: column 4, lines 30-32) and would also have been obvious from column 5, lines 4-5, of Michelson '409.

Art Unit: 3738

The Applicant's remarks have been considered and are adequately addressed in the new grounds of rejection presented above.

The new grounds of rejection were necessitated by the added claim language referenced above. Therefore, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/
Primary Examiner
Art Unit 3738**